UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/007,385	01/15/98	CHU H	0632/0D916

HM21/1222

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EXAMINER	
WEATHERSPOON, J	
ART UNIT	**PAPER NUMBER**
1645	4

DATE MAILED: 12/22/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/007,385	Applicant(s) Chu
	Examiner John K. Weatherspoon	Group Art Unit 1645

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-21* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-21* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Deposit Requirements

1. The specification lacks complete deposit information for the deposit of *Streptococcus equi* (*S.equi*) strain 709-27 (page 5 of the specification). Because it is not clear that the use of live attenuated *S.equi* strain 709-27 possessing the properties of inducing protective immunity as disclosed in the instant application are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the use of *S.equi* strain 709-27, a suitable deposit for patent purposes is required. Accordingly, filing of evidence of the reproducible production of *S.equi* strain 709-27 claimed in instant claims 5, 9, 11, 16 and 18, and dependent claims thereof, is required. Without a publicly available deposit of *S.equi* strain 709-27, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of *S.equi* strain 709-27 is an unpredictable event.

Applicant's referral to the deposit of *S.equi* strain 709-27 on page 5 of the specification is an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR §1.801-1.809 have been met.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under

the provisions of the Budapest Treaty and that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application. These requirements are necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited

material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;
2) The name and address of the depositor;
3) The date of deposit;
4) The identity of the deposit and the accession number given by the depository;
5) The date of the viability test;
6) The procedures used to obtain a sample if the test is not done by the depository; and
7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that *S.equi* strain 709-27 described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to depository coupled with corroboration that deposit is identical to biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §1.801-1.809 for further information concerning deposit practice.

Claim Objections

2. Claims 19-21 are objected to because of the following informalities: the use of the abbreviation "CFU". Appropriate correction to replace the abbreviation with the non-abbreviated phrase is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 5, 10, 15, 17 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by either Timoney (U.S. Patent No. 5,183,659, patented 02/02/93; reference cited by applicant) or Timoney (PCT Publication WO 87/00436, published 1/29/87). Timoney and Timoney each disclose a composition, i.e. a vaccine composition, comprising a live attenuated and non-encapsulated *Streptococcus equi*, i.e. *Streptococcus equi* strain 709-27 (ATCC No. 53186) (see WO 87/00436, page 4 and 5,183,659, column 2), and an immunostimulant, i.e. an M-protein fragment with a molecular weight of about 41,000 (see WO 87/00436, page 12 and 5,183,659, column 8), wherein Timoney and Timoney each disclose that said M-protein fragment stimulates an immunological response in the nasopharyngeal mucosa of an equine. Timoney and Timoney each further disclose a dosage form for nasal administration comprising said composition and a method of stimulating an immune response to *Streptococcus equi* comprising contacting said composition with the nasopharyngeal mucosa of an equine, and a method of protecting an equine against *Streptococcus equi* infection comprising intranasal or oral administration of said composition to said equine, wherin said live attenuated *Streptococcus equi*

is in the amount of from about 10^5 to about 10^{11} CFU, or from about 10^6 to about 10^{10} CFU, or from about 10^7 to about 10^9 CFU (see entire references).

5. Claims 1, 3, 10, 17 and 19-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Hartford et al (European Patent Application No. EP 0 786 518 A1, published 7/30/97; reference cited by applicant). Hartford et al disclose a vaccine composition comprising a live attenuated *Streptococcus equi* and an immunostimulant, said immunostimulant having the property of stimulating the immune system including mucosal (e.g. nasal) immune responses. For example, Hartford et al disclose use of the immunostimulant Carbopol (see entire reference, for example page 3, lines 39-43 of reference), and use of said vaccine for preventing *Streptococcus equi* infection in equine. Hartford et al further disclose that said vaccine may be administered by several dosage forms including intranasal application (see entire reference, for example page 3, lines 10-15), and that said vaccine composition is administered wherin said live attenuated *Streptococcus equi* is in the amount of from about 10^5 to about 10^{11} CFU, or from about 10^6 to about 10^{10} CFU, or from about 10^7 to about 10^9 CFU (see entire reference, in particular "Examples" cited and discussed by Hartford te al). In view of the above-cited disclosure of Hartford et al, the limitations of instant claims 1, 3, 10, 17 and 19-21 are met by the prior art.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Timoney or Timoney (above) in view of Hartford et al (above) and Gerber (U.S. Patent No. 4,806,350, patented 02/21/89; reference cited by applicant). The teachings of both Timoney and Timoney are discussed above.

Timoney and Timoney do not teach the use of saponin as an immunostimulant as stated in the instant claims 4 and 6-8. Hartford et al teach doses of *Streptococcus equi*, e.g. said *Streptococcus equi* taught by Timoney and Timoney, as stated in instant claims 12-13. Timoney and Timoney teach said *Streptococcus equi* 709-27 in a lyophilized form (see references) (i.e. instant claim 14) and Gerber teaches the use of saponin as an immunostimulant in a vaccine composition, wherein said vaccine composition stimulates an immune response in an animal and comprises an immunostimulating, non-toxic amount of a saponin, and further wherein said saponin used to prepare said vaccine includes 5000 micrograms saponin (equivalent to 5 mg) per dose of Quil A emulsifier (see entire reference, for example column 12, wherein Gerber further teaches that said dose of Quil A emulsifier is a one ml dose (see column 11).

The teachings of either Timoney or Timoney in view of Hartford et al and Gerber indicate that it would have been obvious to one of ordinary skill in the art at the time the invention was filed to claim the limitations of the instant claims 1-21 as stated.

Status of Claims

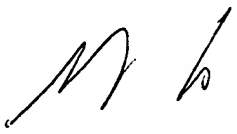
8. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1645 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Weatherspoon, Ph.D. whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached at (703) 308-3995.

John Weatherspoon, Ph.D.

December 4, 1998



Anthony Caputa, Ph.D.

Supervisory Primary Examiner

Group 1645